c.) Remarks

Office Action of October 28, 2005

Claims 1-4, 6, 8-9, 11-15, and 22 are pending. In examiner's office action, the examiner incorrectly states that claims 1-4, 6, 8-9, 11-15, and 17-22 are pending. Claims 16-21 were originally canceled in the amendments filed by applicants with an RCE on July 14, 2004. The remaining claims were subsequently amended in applicants paper filed on February 22, 2005. Thus, the claims which are actually currently pending are those filed in applicant's paper of February 22, 2005. For the convenience of the examiner, the applicants have listed the currently pending claims with status modifiers, despite the fact that no amendments are presently being made. Accordingly, applicants will not address claims 16-21, as these claims have been previously canceled.

The following claim rejection is outstanding:

1) Rejection of claims 1-4, 6, 8-9, 11-15, and 22 under 35 USC § 102(b) as anticipated by or, in the alternative, under 35 USC § 103(a) as being unpatentable over U.S. Patent 4,851,221 to Pak et al (hereinafter, "Pak") in view of the Merck Manual of Diagnosis and Therapy, 17th Ed., 1999 (hereinafter, "Merck Manual") and applicant's admission regarding the prior art on page 2 of the specification (hereinafter, "applicant's page 2").

1. Rejection of Claims 1-4, 6, 8-9, 11-15, and 22 under 35 USC § 102(b) or under 35 USC § 103(a)

The examiner asserts that Pak discloses administration of a calcium supplemental composition comprising calcium citrate at a dose of 1 g (60 meq/day) or 1.5-2.75 g calcium/day to a postmenopausal woman for the treatment of various conditions such as hypoparathyroidism,

osteoporosis, bone loss, hyperphosphatemia, and hypertension. The examiner asserts that Pak discloses a daily administration and that the calcium citrate composition of Pak is prepared from a pre-mix preparation with a calcium/citrate molar ratio of 1.25 of citric acid and a calcium compound such as calcium hydroxide. The examiner also asserts that Pak discloses the same effective amounts or doses of calcium citrate to be administered to the postmenopausal woman as instantly claimed.

The examiner then concedes that Pak does not disclose the employment of the calcium composition in methods of increasing HDL in plasma or ratio of HDL to LDL in a postmenopausal woman, and that Pak does not disclose that if HDL level in plasma is increased, the administration of the calcium composition should continue for at least about two months. Having recognized these deficiencies in the teachings of Pak, the examiner then dismisses them using an improper inherency argument. The examiner cites the Merck Manual for the proposition that the various conditions associated with postmenopausal women include hypercholesterol levels which require an increase in the HDL level or a lowering of the LDL level or increasing the ratio of HDL to LDL in said postmenopausal woman. Based upon, this, the examiner asserts that Pak's patient population encompasses or overlaps or is even the same as that population herein as needing an increase in HDL levels.

Applicants respectfully traverse this rejection. The fact that "cardiovascular diseases become more prevalent after menopause" provides no basis to assert that Pak's teachings inherently disclose the use of calcium supplementation for the treatment of hypercholoesterol levels. The argument of inherency is both unconvincing and improper. Pak makes no claims regarding effects, and therefore it does not make clear to whom one would give a calcium citrate supplement. Calcium is mainly prescribed to women for osteoporosis prevention - these subjects

at risk of osteoporosis do not necessarily have a high HDL, and those with a high HDL are not necessarily at risk of osteoporosis. One could reasonably argue that men often have high HDL and are at low risk of osteoporosis (although the data in the instant application do not relate to men). The way the inherency argument is used by the examiner, it would seem to eliminate any possibility of specific claims regarding new uses of a composition that is already covered by a composition of matter patent (i.e., new uses of a known composition). This is clearly not the law and applicants assert that the rejection is not proper.

Rejections based on inherency cannot be bottomed on mere possibilities; the mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981). In order to support a rejection based upon inherency, the result must necessarily be present in the prior art; it is not sufficient that it may likely be present in some instances, but not in others. Occasional results are not inherent. *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). While some postmenopausal women suffering from osteoporosis may also suffer from a high HDL, this is not necessarily so. A teaching of the use of calcium supplementation for treatment of osteoporosis says nothing about the usefulness, or lack thereof, of using calcium supplementation for treatment of hypercholesterol levels. Therefore, applicants assert that there is no teaching or suggestion in Pak to one of ordinary skill in the art that the employment of the calcium composition is useful in methods of increasing HDL in plasma or ratio of HDL to LDL in a postmenopausal woman, and that if HDL level in plasma is increased, the administration of the calcium composition should continue for at least about two months. This is true notwithstanding any teachings or suggestions at applicant's page 2 that calcium supplementation is widely recommended for postmenopausal women in the treatment of osteoporosis. Pak does not disclose or suggest, either expressly,

inherently, or otherwise, that the employment of the calcium composition is useful in methods of increasing HDL in plasma or ratio of HDL to LDL in a postmenopausal woman, and that if HDL level in plasma is increased, the administration of the calcium composition should continue for at least about two months. The Merck Manual reference is also deficient; it merely provides the unremarkable statement that cardiovascular disease becomes more prevalent after menopause. It cannot be reasonably asserted that because a method is known to be beneficial in treating a certain condition that it is obviously beneficial in treating another condition, simply because the two conditions are more prevalent in older populations. Almost all conditions become more prevalent with advancing age. The secondary references of Merck Manual and page 2 of the applicant's specification also fail to teach or suggest the use of calcium supplementation as claimed in the pending claims. As a result, the secondary references suffer from the same deficiency. Accordingly, the instant claims are patentable over any of these references taken alone and are also patentable over any combination of the cited references, including Pak.

The examiner states that it is well known that calcium supplementation is used for postmenopausal women for treating various conditions. The examiner ignores that fact that what is not well known and what is not obvious, is that calcium supplementation is useful for postmenopausal women for treatment of unhealthy cholesterol levels. What the instant invention teaches is that calcium supplementation is useful for postmenopausal women for treatment of unhealthy cholesterol levels, which is both novel and non-obvious over the cited references.

The examiner then asserts that although Pak does not expressly disclose measuring HDL levels in a postmenopausal woman, it would have been obvious to one of ordinary skill in the art in view of Pak to measure HDL levels when administering calcium citrate for increasing HDL levels. However, this statement disregards the fact that Pak does not teach or suggest the use of

calcium supplementation for treatment of unhealthy HDL levels. It is unclear why the examiner feels it would be obvious to test a patient's cholesterol levels when one is trying to treat or prevent osteoporosis in the patient. Pak doesn't expressly disclose this for the very reason that Pak is not concerned with this.

In light of applicant's arguments, applicants believe that they have overcome the examiner's rejection under § 102(b), or alternatively, under § 103(a), and respectfully request that the examiner withdraw the pending rejection and to allow the pending claims.

d.) Conclusions

In light of the applicants' argument, applicants respectfully request withdrawal of the outstanding rejections and allowance of the pending claims. If any issues remain outstanding, please contact the undersigned for resolution of the same.

Applicants believe that no fees are associated with the filing of this response. However, if applicants are in error and any fees are owing, the Commissioner may charge Deposit Account No. 06-2375, under Order No. P02194US0/10104570, from which the undersigned is authorized to draw.

Respectfully submitted,

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